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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,522	08/13/2001	Michael E. Spurlock	LL31-12.0015	8379

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EXAMINER	
SAOUD, CHRISTINE J	
ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/928,522	SPURLOCK, MICHAEL E.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-86* is/are pending in the application.

4a) Of the above claim(s) *86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *52-85* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06 October 2006 has been entered.

Response to Amendment

Claims 1-51 are cancelled and claims 52-86 have been added. Claims 52-86 are pending in the instant application.

Claim 86 is directed to an isolated protein, which is an invention that has been previously withdrawn from consideration. See Restriction Requirement of 07 March 2003 and election, with traverse, on 07 July 2003. Accordingly, claim 86 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03

Therefore, claims 52-85 are under examination in the instant Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 06 October 2006 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 112

Claims 53-65, 67-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

In the most recent amendment, Applicant has canceled all the previously pending claims and added all new claims. Applicant did not identify in the specification by page and line number the basis for the new claim limitations. After a review of the specification as originally filed, basis for the new claim limitations could not be found. For example, "identity with at least sixty percent of corresponding nucleotide bases at positions", "identity with at least eighty percent of corresponding nucleotide bases at positions", "identity with at least ninety percent of corresponding nucleotide bases at positions", "identity with at least ninety five percent of corresponding nucleotide bases at positions", recited hybridization conditions with optional combinations or for "low salt

concentration of 0.99 M sodium ion", and "an isolated single-stranded DNA molecule, a complimentary RNA strand of the single-stranded DNA molecule". The claims must find basis in the specification as originally filed and Applicant must point out support for the new claim limitations. Therefore, the claims are considered new matter.

Claims 52-85 are rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the written description requirement for the reasons of record as applied to previously examined claims 13-30 and 39-51. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The instant claims are generically directed to isolated DNA and RNA (single and double-stranded) which encode bovine leptin, wherein the nucleic acid molecule hybridizes to a nucleic acid sequence of SEQ ID NO:3 (or a variant thereof) under stringent hybridization conditions. However, the only such molecule disclosed in the instant specification is the nucleic acid molecule of SEQ ID NO:3 which encodes the protein of SEQ ID NO:4.

Applicant argues at page 14 that they are "in actual possession of a bovine leptin genus" and that the "genus of DNA sequences are unique from murine and human at positions 2, 5, 92, 131, 146, 147, 176, 182, 183, 225, 279, 280, 302, 311, 313, 322, 333, 340, 356, 368, 401, 404, 414, or 444 of SEQ ID NO:3". Applicant's argument has been fully considered, but is not persuasive. The specification teaches a single bovine leptin

molecule. A single bovine leptin molecule does not constitute a genus. The specification does not provide written support for the claims which recite these positions (see rejection above for new matter), nor does the instant specification teach any additional bovine leptin molecule which differ at these positions. Therefore, Applicant's argument is not persuasive.

As stated in the previous Office action(s), If one of ordinary skill in the art would not know the bovine leptin sequence until they were in possession of the bovine leptin sequence (as stated by Dr. Spurlock in a 1.132 Declaration, filed 01/18/01 in parent application 08/688,908), it is unclear how the instant claims meet the written description requirement when the specification provides one bovine leptin sequence, but is claiming a vast genus of molecules which have not been isolated or described. Even if one of ordinary skill in the art could use the disclosed polynucleotide sequence to hybridize to bovine polynucleotides, the skilled artisan would not know if they were in possession of bovine leptin as stated so clearly by the inventor himself.

Claims 52-85 are rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the enablement requirement for the reasons of record as applied to previously pending claims 13-30, 39-51. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record.

Applicant argues that the claims subject to the rejection have been canceled. However, the issue remains that the claims are not enabled for molecules which hybridize and encode a bovine leptin. There is no requirement that the molecules which hybridize do so to the complete coding region of SEQ ID NO:3 – this encompasses fragments and the specification is not enabled for fragments which encode a bovine leptin. There are no examples of a single variant of bovine leptin in the instant specification, and there is a but a single example of a bovine leptin in the instant specification. While the skill in the art is high, there is no guidance or direction provided in the instant specification for making mutations or variations to the given coding sequence; there is no disclosure of which regions of the molecule should be conserved or which regions could be variable. Based on the teachings of the prior art, one might expect that the nucleic acid encoding bovine leptin could be varied to some degree (12% based on the conservation with the human protein), but would this molecule still be considered a "bovine" leptin? If the nucleic acid is not present in the cow, can it still be considered bovine leptin. Or if the starting material is from cow, and the molecule is mutated such that it now has the sequence of the human molecule, is it still considered "bovine" leptin? Regardless, the issue is that based on the lack of guidance in the specification and the prior art for only 4-11% identity to the given molecule, the lack of examples, and the degree of unpredictability in the art, the claims are not enabled for the full breadth of the claims, absent evidence to the contrary.

At pages 16-17 of the response, Applicant argues a rejection which has been obviated by cancellation of the claims. Applicant's continued argument is moot, as the issue is no longer applicable to the instant claims.

Claim Rejections - 35 USC § 112/2nd

Claims 52-85 are indefinite for the limitation of "stringent hybridization conditions". The limitation "stringent hybridization conditions" is equivalent to reciting a range without indicating the metes and bounds of the conditions since there is no indication of what conditions are to be encompassed by the claims. The specification does not provide a definition of what conditions are considered "stringent" and the art recognizes a multitude of conditions which could be used and considered "stringent". Because a multitude of conditions are encompassed by the claims, it is not clear which molecules which may hybridize under varying conditions are encompassed by the claims. Many of the claims recite a variety of conditions and indicate that any of the conditions in any combination or all of the conditions are included. This still does not set forth a "set of conditions" by which the nucleic acid molecules will be isolated, therefore, there are still variables unaccounted for which will greatly affect which molecules will hybridize and which will not. Therefore, the metes and bounds of the claims are unclear and the claims are indefinite.

Applicant continues to argue this rejection at pages 17-22. Applicant states at page 21 of the response that "one of ordinary skill in the art will recognize the objective of the claimed invention and would have the knowledge to choose from a variety of

conditions to obtain the stringent conditions required to obtain the ***appropriate final result***" (emphasis added). Herein lies the problem. Without a finite, definite set of conditions, which one of ordinary skill in the art is aware, it is unclear if an "appropriate final result" has been met. The purpose of a definite claim is so that one of ordinary skill in the art knows if they are infringing a patented claim or not. What is considered "appropriate" to Applicant, may be considered new and novel to one of ordinary skill in the art. The metes and bounds of the claims must be clear, and the current claims recite open-ended ranges for obtaining molecules, which makes it impossible to determine if the limitations of the claims are met. Therefore, the claims are indefinite for these reasons and the reasons presented in the previous Office actions.

Applicant argues at pages 22-23 a rejection which has been obviated by cancellation of the claims. Applicant's continued argument is moot, as the issue is no longer applicable to the instant claims.

Claims 66-85 are indefinite for reciting both, an isolated single-stranded DNA molecule and a complimentary RNA strand of the single-stranded DNA molecule. It is not clear if the claims are directed to (1) isolated single-stranded DNA, (2) complimentary RNA, (3) or a complex of the two molecules. Take claim 66 for example, there is no disclosed relationship between the DNA molecule in line 1 and the RNA molecule in line 3.

Based on this ambiguity, no art rejections of these claims can be made at this time. If the claims are amended to clearly indicate that RNA molecules are encompassed, an art rejection may be necessitated by such an amendment.

Claims 72-75 and 82-85 are rejected for lacking antecedent basis. Claim 66 and 76 recite an "isolated single-stranded DNA molecule", but the dependent claims are directed to "The isolated double-stranded DNA molecule". There is insufficient antecedent basis for "the isolated double-stranded DNA molecule" in the base claims.

Applicant's arguments at pages 28-30 regarding the Tellum et al. reference are moot in light of the cancellation of the previously filed claims.

Claim Rejections - 35 USC § 103

Claims 52-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (U.S. Pat. No. 6,309,853) for the reasons of record in the previous Office action(s) as applied to the previously filed claims.

Applicant argues at page 32 that the Friedman patent does not teach, suggest, disclose, or make obvious the invention and that the Friedman patent does not disclose any bovine leptin DNA (or mRNA) molecules or polypeptides.

Applicant's argument has been fully considered, but is not persuasive. Friedman et al. teach that the nucleic acid molecules encoding leptin could be used to isolate nucleic acid molecules encoding leptin from other species, specifically cows (see

column 48, lines 41-57), contrary to Applicant's assertion that "the Friedman patent does not teach, suggest or disclose the invention of the above-identified application". The claims are broadly directed to isolated nucleic acids which encode bovine leptin – based on the known high degree of nucleic acid similarity of the leptin molecules across species (taught in Friedman), the known existence of a bovine leptin molecule (taught in Friedman), motivation to isolate nucleic acid molecules encoding bovine leptin (taught in Friedman) and known methods of isolation of nucleic acid molecules encoding leptin using one species as a probe (taught in Friedman), the invention as a whole would have been *prima facie* obvious in view of Friedman. If one of ordinary skill in the art used the polynucleotides of Friedman et al. to hybridize to bovine polynucleotides using the methods taught in Friedman et al., there is more than a reasonable expectation of success in isolating a bovine version of leptin, especially since Friedman already confirmed that there was a polynucleotide encoding leptin present in cows, absent evidence to the contrary. Applicant has not provided any evidence on the record that one of ordinary skill in the art could not follow the teachings and guidance in Friedman et al. to isolate nucleic acids encoding leptin in cows. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time it was made.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud